REMARKS

Claims 1, 2, 15, 16 and 18-22 are pending in the subject application. By this Amendment, applicants have amended claim 1 to incorporate the language of claim 2, and have cancelled claim 2 without prejudice or disclaimer of applicants' right to pursue the subject matter of this claim in the future. In view of the arguments below, applicants maintain that the Examiner's rejections have been overcome, and respectfully request that they be withdrawn.

Provisional Obviousness-Type Double Patenting Rejection

The Examiner provisionally rejected claims 1, 15, 16 and 18-22 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 27, 39 and 40 of copending U.S. Application No. 10/712,642.

Applicants understand that this is only a provisional rejection, and will respond should the rejection become non-provisional.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected claim 15 as allegedly anticipated by Takiguchi et al. (Genomics, 35:129-135, 1996) in part because "the oligonucleotides disclosed by Takiguchi et al. meet all of the structural limitations of the instantly claimed invention...".

In response, applicants respectfully traverse the Examiner's rejection. Every element of a claim must be taught in a prior art reference for that prior art to anticipate the claim. Applicants note that claim 15 is directed to an antisense oligonucleotide which prevents expression of the human DNA-dependent protein kinase subunit Ku70. In contrast, Takiguchi et al., at the cites given by the Examiner, refers to (1) a forward primer to the mouse sequence, (2) nested reverse primers to the human sequence, and (3) a cDNA probe to genomic mouse sequence.

With regard to the forward primer to the mouse sequence, applicants note that there is no teaching that the mouse primer can specifically hybridize to the human sequence. Specific hybridization necessarily denotes certain structural features by dint of a degree of complementarity with the human nucleic acid. There is no indication in Takiguchi et al. that the oligonucleotides disclosed therein possess this structural feature. In addition, the Examiner's statement that the oligonucleotides disclosed by Takiguchi et al. meet all of the structural limitations of the instantly claimed invention does not take into account the functional characterization of the claimed oligonucleotide, in that the oligonucleotide must both bind and prevent expression of the human DNA-dependent protein kinase subunit, necessarily restricts the structural form that the claimed oligonucleotide has. Thus, the inhibitory nature of the oligonucleotide is based on its structure, and a primer is

not an oligonucleotide that *prevents expression* of the protein from the nucleic acid for which it is a primer. Applicants note that the inhibitory function, and necessary structural limitation that this entails, cannot simply be disregarded by the Examiner. In addition, the Examiner provides no rationale as to how something that is permissive of DNA synthesis will somehow inhibit expression of the protein which the DNA encodes.

With regard to the reverse primer to the human sequence, applicants note that, as analogously argued above with respect to the prior art primers, the inhibitory nature of the instant oligonucleotide is based on its structure, and a reverse primer is *not* an oligonucleotide that *prevents expression* of the protein from the nucleic acid for which it is a reverse primer.

With regard to the cDNA probe to the mouse genomic sequence, applicants note that there is no teaching that such probe can specifically hybridize to the human sequence. Specific hybridization necessarily denotes certain structural features by dint of a degree of complementarity with the human nucleic acid. There is no indication or teaching in Takiguchi et al., and the Office Action provides no rationale, why a cDNA probe to a DNA that is both (i) mouse in origin and (ii) genomic would possess this structural feature.

Accordingly, applicants maintain that Takiguchi et al. does not teach all the elements of applicants' invention as recited in the pending claims, and respectfully request that the Examiner

reconsider and withdraw this ground of rejection.

Rejections Under 35 U.S.C. §103(a)

The Examiner rejected claim 15 as allegedly obvious over Takiguchi et al. (Genomics, 35:129-135, 1996) in part because Takiguchi et al. "teach antisense oligonucleotides that specifically hybridize to a nucleic acid encoding a human DNA-dependent protein kinase subnunit, Ku70" and that the oligonucleotides "disclosed by Takiguchi et al. meet all of the structural limitations of the instantly claimed invention…".

In response, applicants respectfully traverse the Examiner's rejection. In order for an obviousness rejection of the claimed method under 35 U.S.C. 103(a) to be proper, the prior art reference, in combination with ordinary skill, must in part teach or suggest all the elements of the claimed invention. As stated above, applicants again note that claim 15 is directed to an antisense oligonucleotide which prevents expression of the human DNA-dependent protein kinase subunit Ku70. In contrast, Takiguchi et al. teaches (1) a forward primer to the mouse sequence, (2) nested reverse primers to the human sequence, and (3) a cDNA probe to genomic mouse sequence, and none of these possesses all the required structural features, as argued above, of the claimed invention. Moreover, ordinary skill in the art does not cure this deficiency. Accordingly, applicants maintain that the invention as claimed is not obvious over Takiguchi et al. and respectfully request that the Examiner reconsider and

withdraw this ground of rejection.

The Examiner rejected claims 1, 2, 15, 16 and 18-22 under 35 U.S.C. §103(a) as allegedly unpatentable over Takiguchi et al. as applied to claim 15, Reeves et al. and Milner et al., the combination in view of Au-Young et al.

In response, applicants respectfully traverse the Examiner's rejection. Initially, applicants note that with regard to claim 15 and claims dependent therefrom, as argued above, Takiguchi et al. do not teach or suggest an oligonucleotide with the all the structural characteristics of the oligonucleotide claimed by applicants or that employed in the method claimed by applicants, and the remaining cited references in combination with Takiguchi et al. do not cure this deficiency. Moreover, the method as recited in claim 1 requires that the antisense nucleic acid be enclosed in a liposome. None of the references, in combination with all of the others, teaches such *in vitro* administration of the antisense oligonucleotide.

Rejection Under 35 U.S.C. §112, First Paragraph (Written Description)

The Examiner rejected claims 1, 2, 15, 16 and 18-22 under 35 U.S.C. §112, first paragraph, as allegedly not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner indicated that the scope of the claims includes

numerous variants and that the genus is highly variant because a significant number of structural differences between members of the given genus is permitted.

In response, applicants respectfully traverse the Examiner's rejection. Applicants note that the genus of the claim is those antisense oligonucleotides that specifically hybridize to a nucleic acid encoding a human DNA-dependent protein kinase subunit so as to prevent expression thereof. As such, the members of the genus need to possess all of the structural features determined from being (i) an antisense oligonucleotide (ii) that specifically hybridizes to a specific nucleic acid, and that (iii) prevents expression thereof. Thus, while the sequence information may vary among species, the members of the genus do not vary in the requisite structural features set forth in the claims and described in the specification. The single genus encompasses a finite number species whose properties are described, and applicants maintain that the specification in fact describes the *pertinent* structural information that those of skill in the art would recognize as needed to describe the genus.

Those of skill in the *art of the claimed invention* would recognize from the description that the antisense is (i) an antisense oligonucleotide that (ii) specifically hybridizes to (iii) a nucleic acid (iv) encoding a human DNA-dependent protein kinase subunit so as to (v) prevent expression of the human DNA-dependent protein kinase subunit, wherein the subunit is (vi) a

human DNA-dependent protein kinase catalytic subunit, (vii) a Ku70, or (viii) a Ku80, all of which are described in the specification.

Thus, applicants maintain that the specification shows applicants were in possession of the claimed invention at the time of filing. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Conclusion

For the reasons set forth above, applicants respectfully request that the Examiner reconsider and withdraw the rejections, and solicit allowance of pending claims 1, 2, 15, 16 and 18-22.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is

given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents,
P.O. Box 1450
Alexandria, VA 22313-1450.

5/3/06
Alan J. Morrison Date
Reg. No. 37,399

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400